

single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle.

[52 FR 47322, Dec. 11, 1987; 52 FR 48792, Dec. 24, 1987, as amended at 53 FR 18838, May 25, 1988; 55 FR 9722, Mar. 15, 1990; 55 FR 40381, Oct. 3, 1990; 55 FR 50172, Dec. 5, 1990; 64 FR 403, Jan. 5, 1999]

§ 333.150 Labeling of first aid antibiotic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "first aid antibiotic."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "First aid to help" [select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against"] [select one of the following: "infection," "bacterial contamination," or "skin infection"] "in minor cuts, scrapes, and burns." Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor."

(2) *For products containing chlortetracycline hydrochloride or tetracycline hydrochloride.* "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by doctor."

(3) *For any product containing bacitracin, bacitracin zinc, neomycin, neomycin sulfate, polymyxin B, and/or polymyxin B sulfate.* "Stop use and consult a doctor if the condition persists or

gets worse, or if a rash or other allergic reaction develops. Do not use if you are allergic to any of the ingredients. Do not use longer than 1 week unless directed by a doctor."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions": (1) *For ointment and cream products.* "Clean the affected area. Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily. May be covered with a sterile bandage."

(2) *For powder products.* "Clean the affected area. Apply a light dusting of the powder on the area 1 to 3 times daily. May be covered with a sterile bandage."

(3) *For aerosol products.* "Clean the affected area. Spray a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage."

(e) The word "doctor" may be substituted for the word "physician" in any of the labeling statements in this subpart.

[52 FR 47332, Dec. 11, 1987, as amended at 61 FR 58472, Nov. 15, 1996]

§ 333.160 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.